EVALUATION OF THE UTILITY OF IMNCI ALGORITHM IN PREDICTING ILLNESS, HOSPITALIZATION AND MANAGEMENT OF CHILDREN AGED 2 MONTHS TO 5 YEARS IN A TERTIARY REFERRAL CENTRE

Dissertation submitted to

THE TAMIL NADU DR. M.G.R.MEDICAL UNIVERSITY

in partial fulfillment of the regulations
for the award of degree of

M.D DEGREE (PEDIATRICS) BRANCH VII

INSTITUTE OF CHILD HEALTH
AND
HOSPITAL FOR CHILDREN
MADRAS MEDICAL COLLEGE

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CERTIFICATE

This is to certify that the dissertation titled **"Evaluation of the utility of IMNCI algorithm in predicting illness, hospitalization and management of children aged 2 months to 5 years in a tertiary referral centre"** submitted by **Dr. P. Venkatesh,** to the Faculty of Pediatrics, The Tamil Nadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment of the requirements for the award of M.D. Degree (Pediatrics) is a bonafide research work carried out by him under our direct supervision and guidance, during the academic year 2009-2011.

Prof. Dr.V.Kanagasabai, M.D.

Dean,
Madras Medical College,
Chennai – 600003

Prof.Dr.P.Jeyachandran,M.D.,DCH

Director and Superintendent,
Institute of Child Health and
Hospital for Children,
Chennai – 600008

Prof. Dr. C. Subbulakshmi, M.D., DCH,

Professor of Pediatrics,
Institute of Child Health and
Hospital for Children,
Chennai - 600 008

DECLARATION

I, **Dr.P.Venkatesh**, solemnly declare that the dissertation titled "***Evaluation of the utility of IMNCI algorithm in predicting illness, hospitalization and management of children aged 2 months to 5 years in a tertiary referral centre*"** has been prepared by me.

This is submitted to the Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the rules and regulations for the M.D. Degree Examination in Pediatrics.

Place : Chennai
Date :

Dr.P.VENKATESH

Institute of Child Health and Hospital for Children
MADRAS MEDICAL COLLEGE
Halls Road, Egmore, Chennai - 600 008.
Ph : 28191135 / Direct : 28194181 / Fax : 044 - 28194181.

Date......................

Ref.No.Dir/EC/ICH/07

Institute of Child Health and
Hospital for Children,
Chennai-08.
dated:

The Institutional Review Board [Ethical committee] of Institute of Child Health and Hospital for Children, Chennai-08, was held on 30.01.2010 at 10.00AM at the Deputy Superintendents chamber.

Members Present: Dr.R.Kulandai Kasthuri
Chair Person.

Members:
1. Dr.K.Gita
2. Dr.P.Jeyachandran
3. Dr.D.Vijaya Sekaran
4. Prof.Girija Shyam Sundar
5. Mrs.Muthu Lakshmi, (Advocate)
6. Dr.P.Ramachandran
7. Mrs.Shubha Kumar

Member Secretary: Dr.Luke Ravi Chellaiah

Title: "The Evaluation of the Utility of IMNCI ALGORITHM IN PREDICTING ILLNESS, Hospitalization and Management of Children aged less than 5years in a Teritary Referral".

The Institutional Review Board was satisfied with the revised format submitted by you. Hence the Institutional Review Board is pleased to approve the study.

Director and Superintendent.

To,
Dr.P.Venkatesh,
Post Graduate,
ICH & HC,
Chennai-08.

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CONTENTS

INTRODUCTION

Over 10 million children under five years of age die every year around the world. 90% of these deaths occur in South Asia and Sub Saharan Africa. India has around 240 million under five children and contributes close to 25% of under-five mortality[1]. About 70% of such deaths are due to diarrhoea, pneumonia, measles, malaria or malnutrition and often a combination of these conditions[1]. These are also the diseases that are seen to afflict three out of every four sick children seeking care at a health facility. Known and proven cost-effective interventions that can prevent 90% of diarrhea deaths, 62% of pneumonia deaths, 100% measles deaths 92% malaria deaths, 44% HIV/AIDS deaths and 52% neonatal fatalities are available and close to one million under five deaths in India can be prevented through scaling up of such interventions at the primary health care facilities[2].

Sick children seldom have a single illness and even when they present with a single complaint, multiple problems can become evident to a discerning health worker. Hence, a scheme of assessment that is based on the sole presenting complaint is often inappropriate and may lead to failure to diagnose potentially life-threatening problems, which could have been controlled easily, had they been diagnosed when the child had sought care initially[4,5,6].Further, many of the childhood illnesses can present with overlapping complaints. Therefore child health programmes should address the sick child as a whole and not as single diseases[4].

However, peripheral health workers in rural areas who constitute the first point of contact of sick children with the public health care system in India have been accustomed to delivering services under the ambit of vertical health programmes, each of which was focused on one or few diseases, until the recent past. One of the foremost challenges in implementation of an integrated approach in the management of sick children thus lies in the primary health care sector. This workforce needs appropriate training to impart adequate knowledge and skills in the clinical evaluation, appropriate treatment, recognition and referral of children with serious illness and follow-up care in the community. Further, simplified protocols for assessment and management of sick children using an integrated approach and job-aids for use in the field are necessary.

WHO and UNICEF had developed an approach called "Integrated Management of Childhood Illness" (IMCI) with the experience gained from various disease specific control programmes in the early nineties. IMCI adopts a holistic and integrated approach to child health and development. IMCI has three main areas of focus: improving health worker skills, improving health systems and improving family and community practices [4]. For successful implementation of IMCI strategy all the three independent components should be addressed appropriately[6]. IMCI has developed locally adaptable guidelines and algorithms to assist health workers in implementation. These guidelines and algorithms have been refined through research and field tests in various parts of the world by W.H.O. and UNICEF[4].

IMCI guidelines rely on case detection based on simple, easily elicited clinical symptoms and signs that can be picked up by health workers after appropriate training, without the need for laboratory tests. Case management under IMCI is through action- oriented classification, rather than exact diagnoses. This approach permits treatment of several important diseases, and facilitates the treatment of children who present with multiple clinical problems[3]. The core intervention of IMCI approach is integrated case management of five major killer diseases of under five years age namely acute respiratory infection (ARI), diarrhea, measles, malaria and malnutrition and of common associated conditions. IMCI also emphasizes on prevention of childhood diseases and promotion of child health and development through preventive interventions such as immunization, Vitamin A supplementation and nutritional counseling whenever necessary[3,5, 8, 9].

According to the World Bank's 1993 report on Investing in Health, the integrated management of childhood illness is likely to have the greatest impact in reducing the global burden of disease and ranks high among the most cost-effective health interventions in both low and middle income countries[10]. By 2010, IMCI had already been introduced in 75 countries, with varying levels of integration in to country health systems. WHO has undertaken a Multi-Country Evaluation (MCE) to evaluate the impact, cost and effectiveness of the IMCI strategy in Brazil, Bangladesh, Peru, Uganda and the United Republic of Tanzania. The results of the MCE indicate that IMCI improves health worker performance and their quality of care and can reduce under-five mortality and improve nutritional status, if implemented well. It costs up to six times less per child correctly managed than current care. However, it needs to be complemented by activities that strengthen system support and a significant reduction in under-five mortality will not be attained unless large-scale implementation in a country is achieved[11,12]. Other studies have shown that after IMCI introduction, 37 countries have revised and updated their child health policies and 17 have stream lined their essential drugs list for children. Improvements in the primary level health care facilities in countries like Nepal and Uganda have been documented. Improvements in immunization status, availability of weighing scales, ORS and vitamin A, increase in exclusive breast feeding and weight gain among children due have also been linked to adoption of IMCI approach[5].

India has implemented an adaptation of the generic IMCI algorithm to include assessment and management of neonates and young infants called the Integrated Management of neonatal and Childhood Illness (IMNCI), as part of the Reproductive and Child Health Programme II and the National Rural Health Mission. The IMNCI package has been developed by child health experts and has been endorsed by the

Indian Academy of Pediatrics and National Neonatology Forum[5,6]. Frontline health workers including auxiliary nurse midwives (ANMs), staff nurses and medical officers are being trained in the implementation of IMNCI across all Indian states. IMNCI has been introduced in the undergraduate medical curriculum. However doubts about the utility of the approach in the Indian setting have continued to persist among the medical professionals, which is one of the factors that have hindered smooth roll-out of the programme.

Previous research in India has verified the validity of the IMNCI algorithms in detection of serious illness and initiation of appropriate management in India[13,25,26]. These studies have also shown that the IMNCI algorithm has a few shortcomings such as reliance on fast breathing to classify pneumonia which leads to wrong labeling of cases of bronchial asthma as pneumonia. The criteria used for diagnosis of malaria lead to over or under- diagnosis of the condition and consequently, inappropriate treatment. Scope exists for further refinements in the algorithm. No evaluation of the IMNCI algorithm has been undertaken in South India which differs from North India in terms of socioeconomic profile, epidemiology and functioning of the health system. Any revision of the IMNCI algorithms can be undertaken at the national level only when reliable information is available from all parts of the country. Hence the present study was undertaken to evaluate the WHO/UNICEF algorithm for Integrated Management of Childhood Illness (IMNCI) among children aged two months to five years, in Chennai, South India.

REVIEW OF LITERATURE

Shah D., et al.[13] conducted a prospective observational study with 203 children between age of 2 months to 5 years in the outpatient Department (n=101) and Emergency Room (n=102) of Maulana Azad Medical College Hospital, New Delhi, from May 1996 to January 1997. Every study child was assessed, classified and treatment steps identified as per IMCI algorithm by a pediatric post graduate trainee. Then every study child was subjected to protocols of the treating unit. Based on this final diagnoses were made and therapies instituted, which were considered as the “gold standard”. The data was computed and analysed for diagnostic and therapeutic agreements between the “gold standard” and the IMCI and vertical (split IMCI) algorithms. As per gold standard, among 203 children evaluated 78 (38.4%) were hospitalized, 44 (21.7%) were under observation for not more than 24 hours and the rest 81 (39.9%) sent back after initial evaluation and two thirds of children 135 (69.%) had two or more co-existing morbidities. The mean (SD) numbers of morbidities as per “ gold standard”, IMCI low malaria risk category, and IMCI high malaria risk category were 2.1 (1.10), 1.8 (1.0) and 2.2 (1.1) respectively. Study children having any of referral criteria as per IMCI algorithm had greater co-existence of illness (mean 2.5 ± 1.1Vs 1.6 ± 0.8, P < 0.001). The referral criteria in IMCI algorithm proved useful in predicting hospitalization and a combination of hospitalization and observation: their sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and odds ratios with 95% confidence interval (95% CI) were 81% and 69%; 74% and 85%; 66% and 88%;86% and 65% and 11.7 (5.6 – 24.1) and 12.7 (5.9 – 28.1) respectively. IMCI algorithm covered 92% of the recorded illnesses. Total agreement of 129 (63.5%), 110 (54.2%) and 93 (45.8%) respectively were noted for IMCI malaria low risk category, malaria high risk category and vertical (split IMCI) algorithms. Diagnostic discordance of IMCI algorithm and gold standard was primarily due to an under-diagnosis of bronchial asthma and bronchiolitis and due to an over-diagnosis of pneumonia and malaria. Diagnostic discordance of vertical algorithm was primarily due to under-diagnosis. IMCI provided missed opportunity for immunization to be 16.3% of total subjects, whereas in vertical algorithm this provision was not available.

Kalter HD., et al. carried out a prospective study with an objective to validate and improve the content of IMCI referral guidelines at the out patient department and emergency department of Dhaka Shishu Hospital in Dhaka, Bangladesh between September 1994 to February 1995[14]. The patients enrolled were divided into two groups based on age, as 1 week to 2 months and 2 months to 5 years. All clinical data collection and evaluation of enrolled patients including items in IMCI guidelines were done by two experienced Bangladesh Pediatricians. Cases were enrolled preferentially from Emergency room. Data were analysed by using Epi Info Computer Software. Using the pediatrician's assessment of a need for admission as the standard, the sensitivity and specificity of the IMCI guidelines for correctly referring patients to hospital were examined. The IMCI's sensitivity for a pediatrician's assessment in favour of hospital admission was 84% (95% Confidence Interval (95% CI) : 75 – 90) for age group of 1 week to 2 months and 86% (95% CI : 81-90) for age group of 2 months to 5 years, and the specificity was respectively 54% (95% CI : 45-63) 64% (95% CI : 59-69). These results show the IMCI referral guidelines have good sensitivity in a developing country setting with low prevalence of malaria.

Simoes EAF., et al. evaluated the performance of six health workers following a 9- day training course on Integrated Management of Childhood Illness (IMCI) by an observational study of three weeks duration in the month of August immediately following training in Gondar District, Ethiopia[15]. During training period health workers were trained in areas of assessment, classification and treatment of sick children (aged 2 months to 5 years) and on counseling of their mothers. Health worker's performance was evaluated in same areas by the pediatrician by direct observation or independent assessment of child using IMCI algorithm. A total of 449 sick children were evaluated during the study period, almost half were at Gondar Polyclinic (224), rest at Teda. 87% complaints volunteered by mothers were covered by IMCI guidelines. Health workers assessments and classifications were compared with that of pediatricians. The assessment of commonly seen sign (Tachypnea, ear pain) or easily identifiable signs (slow return after skin pinch, wasting, pedal oedema) was good with sensitivities of 67-91%, whereas the assessment of uncommonly seen signs (dry mouth, corneal clouding) or less easily identifiable signs (Eyelid pallor, absence of tears) had a fair or poor sensitivity of 20-45%. The classification of pneumonia, diarrhea with signs of dehydration and malnutrition showed sensitivities of 88%, 76% and 85% and specificities of 87%, 98% and 96% respectively. Classification of febrile illness had a sensitivity of 39%. Completeness of treatment improved from 69% to 88% over the three weeks period. Health workers usually counseled mothers appropriately.

Perkins BA., et al. compared the performance of a minimally trained health worker using the draft IMCI algorithm with that of a fully trained pediatrician at the out patient pediatric clinic of Siaya District Hospital in Western Kenya over 14 months between June 1993 to September 1994[16]. This prospective study enrolled 1795 children aged between 2 months and 5 years. All the children in the study were evaluated using IMCI algorithm by health workers who had completed this training. Then the child was evaluated by physician without knowledge about health worker's assessment. Pediatrician observations were considered as gold standards and comparison done with health worker's observations. Among the presenting complaints 86% were directly addressed by IMCI algorithm. 1210 (67%) children had Plasmodium falciparum infection and 1432 (80%) met the WHO definition for anaemia (Haemoglobin < 11gldl). The sensitivities and specificities for classification of illness by the health worker using IMCI algorithm compared to the diagnosis by physician were: Pneumonia (97%, 49%); dehydration in children with diarrhea (51%, 98%); malaria (100%, 0%), ear problems (98%, 2%) and nutritional status (96%, 66%) respectively. The sensitivity and specificity for IMCI referral guidelines were 91% and 77% respectively.

Weber MW., et al. evaluated the prototype of sick child algorithm in 440 Gambian children aged between 2 months and 5 years, at the outpatient department of Medical Research Council (MRC) Laboratories in Fajara, Gambia, between May 1993 and April 1994[17]. The children were first assessed by a trained field worker using IMCI algorithm and then by a Pediatrician whose clinical diagnoses was supported by appropriate laboratory investigations and whose assessment was considered as gold standard. In this study, treatment options of IMCI algorithm were not evaluated, except for referral of children for hospital admissions. Compared with pediatrician's diagnosis, the sensitivity and specificity of IMCI algorithm were 81% and 89% for the detection of pneumonia, 67% and 96% for dehydration, 87% and 8% for malaria **pa**rasitemia, 100% and 9% for malaria parasitemia above 5000 parasites/ul, 100% and 99% for measles, 31% and 97% for otitis media, 89% and 90% for malnutrition respectively. The sensitivity and specificity of IMCI referral guidelines were 45% and 93% respectively. Majority of presenting complaints were addressed by IMCI algorithm. Most common problems not dealt by chart were skin rashes (12%), mouth problems (8%), and eye problems (6%).

Kostad PR., et al. tested one component of IMCI algorithm (assessment and classification) in the outpatient department of rural district hospital, Kabalore District, in Western Uganda from 15 August 1994 to 27 January 1995[18]. This was a prospective study which compared the evaluation of a medical assistant using IMCI algorithm with the clinical evaluation of the medical officer, who was supported by laboratory investigations. 1226 children aged between 2 months and 5 years were compared. Among this sample, 69% were classified into more than one symptoms category. 6.5% had symptoms that did not belong to any of the IMCI categories. The median number of reference standard diagnosis was two. In 10% of all children, medical officer's diagnosis was not in the reference diagnoses established for the study. 16% were classified into severe category, for which urgent hospital referral was needed. The sensitivity and specificity for referral criteria was 41% and 91% respectively.

Gove S., et al. have described the field test of the WHO/UNICEF training course conducted by WHO Division of Child Health and Development in Arusha, United Republic of Tanzania with an objective to determine whether the training material were effective in preparing participants to manage sick children correctly[19]. A total of 23 first level facility health workers of three types; 8 medical assistants, 8 rural medical aides and 7 MCH (maternal and child health) aides underwent a 11-day training course on integrated management of childhood illness (IMCI), and then were subjected to field test. All data of participants performance were analysed. Over all, the rate of correct classification based on main symptoms, nutritional status and feeling problems was 88% (77% - 100%). When the correct assessment was categorized by degree of severity, correct assessment of signs and symptoms in severe group was only 81% compared with 91% in other categories and the correct classification was much lower in severe group (64%) than other groups (>90%). Overall 86% of cases were counseled correctly. In 77% of total cases treatment was correctly identified.

Paxton LA., et al. evaluated the usefulness of 13 clinical indicators suggesting severe pediatric illnesses in a rural district of Western Kenya among children aged between 2 months and 5 years[20]. This was a prospective study enrolling the subjects from both the out patient department of Siya District Hospital from August to December 1993 and inpatient services of Siya District Hospital from June to November 1993 in Siya District, Western Kenya. Each child was initially evaluated by a trained health worker. Then independent evaluation was carried out by staff physician and the outcome was recorded. Data was computed and analysed. Analysis showed 27% of children seen in outpatient clinics had one or more of the signs of severity. Presentation with any of these signs led to 3.2 times increased likelihood of admission. 54% of hospitalized children had no such signs and 21% of children sent home from out-patient clinic had at least one sign. Among inpatients, 58% of all children and 89% of children who died had been admitted with at least one sign. Abnormal mental status was the sign most highly associated with death (OR = 59.6), followed by proof skin turgor (OR = 5.6). Overall, the mortality risk associated with having at least one sign was 6.5 times higher than that for children without any sign.

Kolstad PR., et al. compared the treatment prescribed by hospital medical officers with the indicated treatment by IMCI disease classifications. This was a prospective study done in the out patient department of Kaborale district hospital in Western Uganda from 15th August 1994 to 27 January 1995[21]. The study population comprised 1226 children aged 2 months – 59 months. The average duration of consultation was 7.2 minutes. Medical assistants misclassified 138 (13%) children. As per IMCI algorithm 16.2% of children had referral to hospital admission, compared with 22% referred by the medical officers. 56% of children had an antibiotic recommended by the IMCI guidelines, while 77% had an antibiotic prescribed by the medical officers. Recommendation of injections was for 11% of children by IMCI and 28% by medical officers. Use of IMCI could have reduced the cost of medication to US $ 0.17 per child compared to the treatment cost of US $ 0.82 as prescribed by medical officers. Medical officers prescribed both greater number and greater variety of drugs than indicated by the IMCI algorithm.

Boulanger LL et al. compared the cost of drugs actually prescribed to a sample of 747 sick children aged 2-59 months in all the rural health facilities in Vihiga district and Bungoma district in Western Kenya with the cost of drugs had the children been managed using IMCI guidelines[22]. The study was conducted between 26 July and 5 August 1994. One of the four survey teams visited each of 36 rural health facilities in the study area on one randomly selected week-day during study period. All sick children aged 2-59 months who were seen at health facility were eligible for inclusion in survey. After consultation by health worker, information was collected and the child was examined by clinical officer using IMCI guidelines and treatments were identified. Data was analysed and compared. As per health worker assessment average illness per child was 1.8 and 2.8 per child based on IMCI guidelines. The average cost of drugs actually prescribed per child was US $ 0.44 (1996 US$). Antibiotics accounted for 77% of total drug cost, with phenoxymethyl penicillin syrup accounting for 59% of total drug cost. Of 295 prescriptions for phenoxymethyl penicillin syrup, 223 (76%) were for treatment of colds or cough.

The cost of drugs that would have been prescribed had the same children been managed with the IMCI guidelines ranged from US $ 0.16 per patient (based on a formulary of larger dose tablets and home remedy for cough) to US # 0.39 per patient (based on a formulary of syrups or pediatric dose tablets and a commercial cough preparation).

Factor SH., et al. evaluated the fever module in the WHO/UNICEF guidelines for IMCI with an object to determine whether this module identifies the children with bacterial infections in an area of low malaria prevalence[23]. This was a prospective study done in out patient department of Dhaka Sishu Hospital, Dhaka, Bangladesh. A systematic sample of 669 sick children aged 2-59 month was enrolled and 666 children were assessed. Each study subject was evaluated initially with IMCI guidelines for fever and then evaluated by pediatrician.

Data were analysed using SAS software. The sensitivity and specificity of current IMCI guidelines for identifying children with bacterial infections and treating them with antibiotics were 78% and 47% respectively. Majority of children with meningitis (100%), pneumonia (95%), otitis media (95%), urinary tract infection (83%), 50% or less of children with bacteremia (50%), dysentery (48%), and skin infection (30%) would have received antibiotics as per IMCI guidelines.

Kahigwa E., et al. assessed the inter-observer agreement in identification of a range of 24 clinical signs associated with various disease presentations in pediatric department of St.Francis Designated District Hospital Ifakara, southern Tanzania between January and June 1999[24]. The study population comprised of 327 children aged between 4 months and 6 years, admitted to pediatric ward with diagnoses of malaria, pneumonia, diarrhea, anaemia or malnutrition. Clinical examinations were performed independently by 2 clinical officers within 1 hour of each other. Data were recorded and analysed. The Kappa-statistic was used to assess inter-observer agreement for each sign. Physical signs involving inspection were more likely to be agreed upon by clinician than the signs involving auscultation. The signs included in IMCI algorithm were found to be largely appropriate (Kappa-scores > 0.41) although there was only a fair agreement (Kappa-score: 0.21 – 0.40) in detection of neck stiffness and chest in-drawing and slight agreement in the detection of dehydration (Kappa- Score 0.199).

Jain et al. compared the physicians' diagnosis with IMNCI algorithm generated diagnosis in 222 hospitalized children aged 2 – 59 months in the Department of Pediatrics, Chattrapati Shahhuji Maharaj Medical University, Lucknow, India, over a period of seven months, from October 2003 to April 2004[25]. All patients between the age of 2-59 months admitted with one or more IMNCI general danger sign were included in the study. A single Pediatric resident examined the children for the presence of general danger signs. Every child was classified according to the WHO/UNICEF algorithms for IMNCI. These were termed as "IMNCI diagnoses". The hospital diagnoses at the time of discharge were considered as the "Physician's diagnoses". The diagnostic agreements between the Physician's diagnosis and the IMNCI diagnosis were computed. Complete agreement on all diagnoses in a single patient was seen in in 41 (18.5%), partial agreement in 132 (59.5%) and total disagreement in 49 (22%) patients.

Kundra et al. assessed the utility of the Indian adaptation of the IMNCI algorithm among 309 children attending the OPD or emergency services of the Department of Pediatrics, Christian Medical College, Ludhiana[26]. The children were assessed and classified according to the IMNCI algorithm and the final diagnosis made after detailed evaluation and relevant investigations, served as the gold standard. The diagnostic and therapeutic agreements between the gold standard, IMNCI and vertical (on the basis of primary presenting complaint) algorithms were computed. Coexistence of illness was observed in 75% of children as per IMNCI algorithm. The referral criteria proved useful in predicting hospitalisation with high sensitivity and specificity (99.3% & 97.3%). IMNCI algorithm covered majority of recorded illnesses. A total agreement with IMNCI was found in 88.4% cases, while total disagreement was seen in 34.5% cases. Corresponding figures for vertical program were 88% and 18.6%. The difference was primarily due to under-diagnosis. The diagnostic discordance of IMNCI and gold standard was evident for the cough category due to under-diagnosis of bronchial asthma and bronchiolitis and an over-diagnosis of pneumonia. Immunization and nutritional counseling was done in 52% of total children compared to 27.5% and 15.5% respectively in gold standard.

Gupta R et al evaluated the utility of the WHO/UNICEF algorithm for integrated management of childhood illness (IMNCI) in infants between the ages of 1 week to 2 months attending the Outpatient Department (n = 70) and Emergency Room (n = 59) at the Department of Pediatrics, Maulana Azad Medical College, New Delhi between May 1997 to February 1998[27]. All subjects aged between 1 week to 2 months, who presented to the Outpatient Department or Emergency Room of the hospital for a fresh episode of an illness, were eligible for enrollment in the study. Every study infant was assessed and classified according to the IMNCI guidelines, treatment steps identified and information was recorded in a proforma. A pediatric post-graduate trainee (RG) performed this assessment during the second year of the residency program. The study subjects were then assessed, examined and managed according to the protocol of the treating unit under the supervision of faculty and/or pediatric senior residents. All relevant investigations (including blood counts, chest radiograph, stool examination, blood cultures, lumbar puncture, etc.) were performed on the basis of history and detailed clinical examination. Based on this detailed clinical evaluation and relevant investigations, final diagnoses were made and therapies instituted. These diagnoses and treatments were considered as the ‘gold standard’. More than one illness was present in 97 (75.2%) of subjects. IMNCI algorithm covered majority (81-84%) of the recorded diagnoses either partly (40-41%) or fully (40-44%). The referral criteria proved quite sensitive (86-87%) in predicting hospitalization but had a lower specificity (53-58%). A total agreement with IMNCI was found in 60-66% cases. The mismatch (34-40%) was more commonly of an over-diagnosis (21-23%) rather than under-diagnosis (15-21%). The sensitivity of the algorithm to identify serious bacterial infection was high (96.1-96.5%) while the specificity was relatively low (51.8-59.7%). Two important conditions identified for possible refinement in the algorithm were URI and breast fed stools.

Kaur et al have assessed the valididty of the IMNCI algorithm for young infants (0 - 2 months) attending the outpatient department and emergency room of Department of Pediatrics, Lady Hardinge Medical College hospital in New Delhi, India during the period April 2005 to February 2006[28]. 419 infants (176 between 0-7 days, 243 between 7 days–2 months) underwent assessment, classification and identification of treatment as per IMNCI algorithm. These babies were also evaluated through a detailed diagnostic assessment and treatment as per the standard protocol of treating unit. The efficacy of IMNCI algorithm to correctly identify sick young infants requiring referral was evaluated in terms of its sensitivity and specificity to identify cases who received in-patient treatment as per the gold standard. Further, broad diagnostic and therapeutic agreements between the gold standard and IMNCI were also compared. The IMNCI algorithm covered 80% of the diagnoses and could identify serious bacterial infection with a sensitivity and specificity of 88.5% and 57.4% respectively. It had sensitivity of 97%, 94% and 95%, and specificity of 85%, 87% and 87% in 0-7 days, 7 days–2 months and 0-2 months age groups respectively. Complete diagnostic agreement with gold standard was seen in 50%; over-diagnosis and under diagnosis was seen in 13% and 19%, respectively.

Low birth weight and upper respiratory infection were the main reasons for over-diagnosis whereas surgical conditions resulted in under-diagnoses in majority.

OBJECTIVE OF THE STUDY

To evaluate the utility of the WHO / UNICEF guidelines for "Integrated Management of Neonatal and Childhood Illness" among children aged two months to five years attending an Urban centre.

MATERIAL AND METHODS

Study Design : Prospective observational study

Study Place : The outpatient department and emergency room, The Institute of Child Health and Hospital for Children, Egmore, Chennai – 600 008.

Study Period : January 2010 to September 2011 (21 Months)

Study Population

Inclusion Criteria

Children attending the out patient department and emergency room aged between 2 months and 5 years for the first time for a fresh complaint due to any illness.

Exclusion Criteria

- Children, who already received treatment for the present illness
- Children with injuries and other external causes of morbidity such as poisoning

Sample size: '300'

A sample size of '300' was decided based on findings from a previous study from Delhi[8]. For the reference study to detect a difference of 5% in diagnostic agreement from gold standard with 90% power and an alpha error of 0.05, the required sample was 203. It is assumed that recruiting 300 subjects can sufficiently power the study to detect even subtler differences than 5%

Recruitment of subjects

Children who visited the OPD or emergency rooms during the study period were randomly selected and screened for inclusion and exclusion criteria by the pediatric post- graduate trainee conducting the study. The parents / guardians of those children who met the inclusion criteria were approached for explanation of the study protocol and consenting.

Methods

Once parents or guardians accompanying the children selected for the study provided verbal consent for participation, their identification details and socio-demographic particulars were noted in a proforma developed for the study. The children were evaluated using the WHO/ UNICEF algorithm for Integrated Management of Childhood Illness. Each study subject was assessed and classified according to IMNCI guidelines and the treatment options were identified and recorded in a proforma (appendix). Each child was evaluated using IMNCI algorithms for high malaria risk areas and low malaria risk areas. The IMNCI algorithm was split in to four modules dealing with specific complaints (cough/breathing difficulty, diarrhea, fever, ear problems) and the classification and treatment options arrived at for each child on applying the specific split algorithms guided by the presenting complaints were also noted. Immunization status was checked for each child according to the IMNCI guidelines and appropriate action taken to utilize the missed opportunities. Nutritional counseling was offered to parents of all children in the study. Appropriate nutritional interventions were undertaken for the management of malnourished subjects.

All children were assessed through detailed history and thorough clinical examination. Management options were decided under the supervision of faculty members (Assistant Professors). All relevant investigations as dictated by the provisional diagnosis and treatment options being considered were performed. These included complete blood count, peripheral smear, urine routine examination, stool microscopy examination, x-ray chest, ultrasonogram, computerized tomographic scan, biochemical investigation, lumbar puncture, cultures etc were performed. The opinion of specialists was sought whenever needed. The final diagnoses and therapeutic procedures were noted from the patient records on the same day while leaving the hospital for children advised home-based care. For children advised admission or observation, the diagnoses and treatment decisions were captured from the case- sheets at the time of their discharge from the hospital. These final diagnoses and treatment decisions were considered as the gold standard.

The treatment options according to the gold standard were grouped into three categories namely hospitalization, observation for a period not more than 24 hours and sent home after initial evaluation. Hospitalized children were followed up till discharge or death. Children who were sent home immediately after evaluation and after some time of observation were asked to come for routine follow-up after 2-5 days to determine the outcome.

For each child, information on diagnosis and treatment was thus available from at least four evaluation streams; gold standard, IMNCI high malaria risk algorithm IMNCI low malaria risk algorithm and one (or more) split IMNCI algorithms. All diagnoses and treatment categories were tabulated manually and the diagnostic and therapeutic agreements were compared. Total disagreement was considered when none of the diagnoses made using the IMNCI algorithms matched with the gold standard diagnoses. When some but not all of the IMNCI diagnoses matched with the gold standard diagnoses, it was considered as Partial agreement.

Statistical analysis

Measures of validity such as Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and Odds Ratio with 95% Confidence Interval (OR 95% CI) were computed for the IMNCI algorithm. The proportion of diagnostic/therapeutic agreements and disagreements were calculated for each IMNCI algorithm and split algorithm. For assessing statistical significance, tests such as Chi-Square test, Chi-Square test for linear trend, Paired and Unpaired Student-t test and Kappa statistic were employed.

Mean number of illnesses diagnosed using the gold standard and high malaria risk IMNCI, low malaria risk IMNCI and vertical (Split IMNCI) algorithms was evaluated for statistical significance using Paired student-t test. The mean number of morbidities between the study children with and without referral criteria was also compared using the paired t test (Table 5). Chi-Square test for trend was applied to assess the trend between the number of General danger signs and the severity of illness.

Kappa statistic with 95% confidence intervals was calculated to estimate nature of therapeutic agreement between gold standard and IMNCI algorithms.

All statistical analyses were performed using SPSS Version 13.

RESULTS

Three hundred children aged between 2 months and 5 years, attending the Pediatrics OPD or emergency room at the Institute of Child Health, between January 2010 and September 2011 were enrolled in the study.

About 56.3% (169) were recruited from the out- patient department, and the rest from emergency room visits (Table 1)

Table – 1. Proportion of Cases from Out-patient Department (OPD) and Emergency Room (ER) (n=300)

Hospital setting	No. of subjects enrolled	% of Total
Emergency Room	131	43.67%
Out-patient Department	169	56.33%
Total	**300**	**100%**

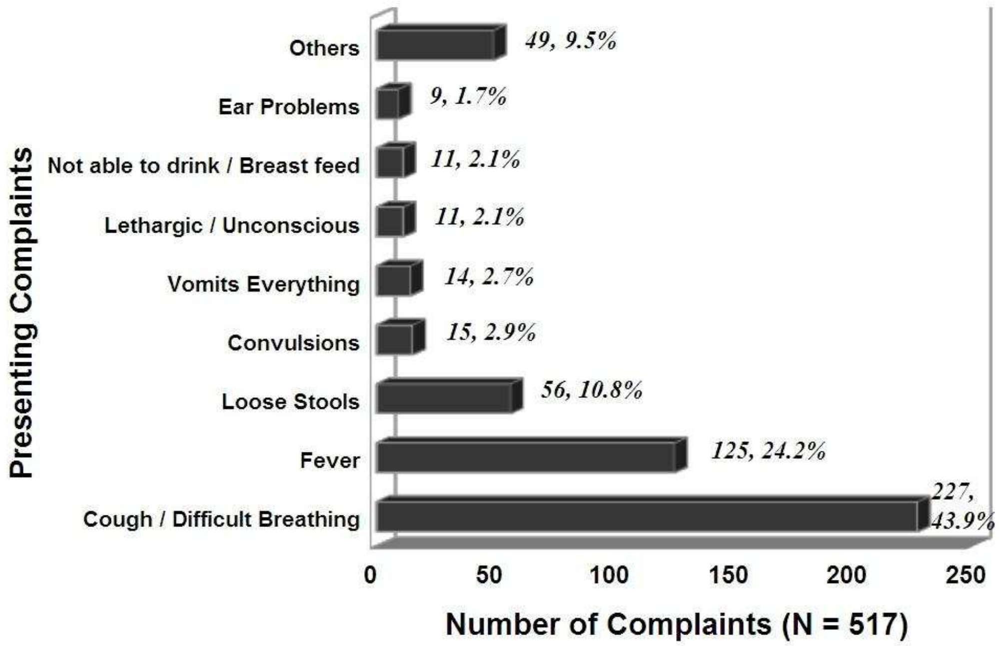
Table – 2. Age and Sex distribution of study population (n = 300)

Age Group	Male		Female		Total	
	No.	%	No.	%	No.	%
2 months – 12 months	21	7.00	25	8.33	46	15.33
13-24 months	46	15.33	43	14.33	89	29.67
25-36 months	41	13.67	32	10.67	73	24.33
37-48 months	31	10.33	27	9.00	58	19.33
49-60 months	16	5.33	18	6.00	34	11.33
Total	**155**	**51.67**	**145**	**48.33**	**300**	**100**

Male vs Female: $\chi^2 = 1.62$, $p = 0.805$

Table 2 presents the age and gender distribution of the study sample. 155 (51.7%) of children who participated in our study were males and 145 (48.3%) females. Children aged 2 months to 12 months constituted 15% of the study participants. About 30% of participants were aged 13 to 24 months, while another 24% belonged to the 25 to 36 months age group. Children aged four to five years comprised only 11% of the study sample. No significant differences in the age distribution between genders were appreciated in the sample.

Fig1. PRESENTING COMPLAINTS OF CHILDREN IN THE STUDY SAMPLE



517 complaints were reported by the parents/other caregivers accompanying the children enrolled in the study; an average of 1.72 complaints per child. Figure 1 depicts the frequency of these symptoms. Over 43% (227) of such complaints comprised of respiratory problems such as cough or difficulty in breathing. One fourth of all presenting complaints (125) were fever and another 10% (56) consisted of loose or bloody/mucoid stools. Other complaints frequently reported were convulsions (15, 2.9%), vomiting everything (14, 2.7%), lethargy/unconsciousness (11, 2.1%), not being able to drink/breast feed (11, 2.1%) and ear problems (9, 1.7%) (Figure1). These aforementioned symptoms, which comprised 91% of reported symptoms, could all be covered by the IMNCI algorithms. Some 9% (49) of complaints were not addressed by the IMNCI algorithms (Figure 2). These consisted of: worms in stools and perianal itching (12, 2.3%), skin lesions (9, 1.7%), crying during micturition or difficulty in micturition or ballooning of prepuce (6, 1.2%), jaundice (5, 0.9%), abdominal pain (4, 0.8%), pedal oedema (3, 0.6%), abdominal distention (3, 0.6%), facial puffiness (3, 0.6%), not attained head control (2, 0.4%), not passing stools 1 (0.2%) and abnormal movements (1, 0.2%).

Fig 2. PRESENTING COMPLAINTS OF CHILDREN IN THE STUDY SAMPLE

Proportion addressed by IMNCI algorithm

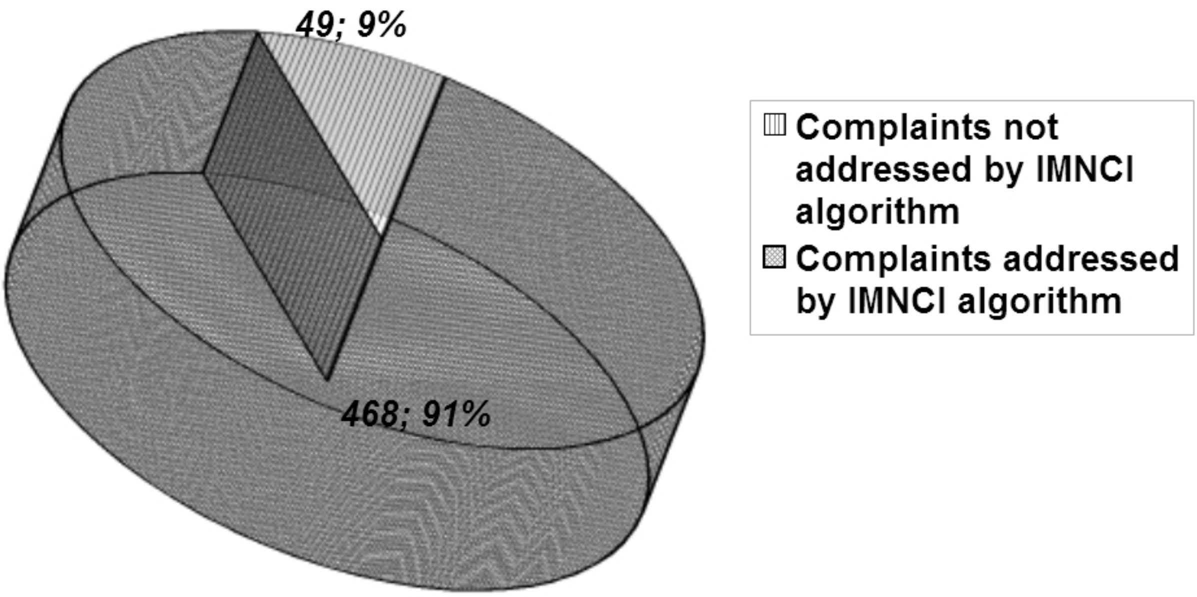


Table – 3. Comparison of morbidities for Gold standard and IMNCI diagnoses (n = 300)

Illness	Gold Standard (No.)	IMNCI Algorithms		
		High Malaria Risk (No.)	Low Malaria Risk (No.)	Vertical split Algorithms (No.)
Respiratory Illness	188	213	213	132
URI/No Pneumonia	80	94	94	31
Pneumonia	51	56	56	44
Severe Pneumonia / Very severe disease		63	63	57
Bronchiolitis	22			
WALRI	25			
Bronchial Asthma	4			
Empyema	2			
Tuberculosis	2			
ALTB	2			
Diarrheal Illness	89	94	94	85
AWD/Diarrhea with no dehydration	50	52	52	45
AWD/Diarrhea with some dehydration	21	24	24	22
AWD/Diarrhea with severe dehydration	2	4	4	4
Dysentery	9	9	9	9
Chronic diarrhea	5			
Persistent diarrhea		3	3	3
Severe persistent diarrhea		2	2	2
Cholera	2			
Febrile Illness	76	183	183	107
Very severe febrile disease		48	48	67
Malaria	10	131	12	9
Fever Malaria unlikely			119	27

Illness	Gold Standard (No.)	IMNCI Algorithms		
		High Malaria Risk (No.)	Low Malaria Risk (No.)	Vertical split Algorithms (No.)
Measles	4	4	4	4
Clinical Malaria	5			
Meningitis	11			
Meningoencephalitis	2			
Enteric fever	9			
Dengue	13			
Urinary tract infection	15			
Viral fver	5			
Septicemia	2			
Ear problems	19	19	19	8
Mastoiditis				
Acute ear infection / ASOM	9	9	9	2
Chronic ear infection / CSOM	10	10	10	6
Others	63			
Malnutrition	114	114	114	114
Severe malnutrition / Very low weight for age	32	41	41	41
Low weight for age / PEM	82	73	73	73
Anemia	162	172	172	172
Severe anemia		11	11	11
Anemia	162	161	161	161
Total (Excluding Malnutrition & Anemia)	435	509	400	332
Total	711	795	686	618

*Other diseases that were diagnosed using the gold standard included: worm infestations (16), febrile seizures (9), seizure disorder (7), pyoderma (4), scabies (4), nephrotic syndrome (4), congenital heart diseases (3), developmental delay (3), acute hepatitis (3), breath holding spell (3), encephalopathy (2), mental retardation (2), shock (1), congenital adrenal hyperplasia (1), congenital megacolon (1).

The gold standard diagnostic process yielded 711 illnesses in the study children. Over one-fourth (26.4%) of these illnesses were of the respiratory system, followed by diarrheal diseases (12.5%) and febrile illnesses (10.7%). Ear infections (19, 2.7%) and other diseases (63, 8.9%) were also diagnosed. 114 children (38%) were diagnosed to be malnourished and 162 (54%) were found to be anemic.

The most common respiratory illness diagnosed was upper respiratory infection (42.6%), followed by pneumonia (27.1%). Bronchiolitis and WALRI contributed about 3% each. Other respiratory diseases included bronchial asthma, tuberculosis, empyema and acute laryngotracheobronchitis. More than half the cases with diarrheal diseases had no symptoms of dehydration at presentation. Severe dehydration was present only in 2 children. 9 cases of dysentery and 5 cases of chronic diarrhea were also diagnosed. The febrile illnesses included malaria, enteric fever, dengue, measles, meningitis, meningoencephalitis, urinary tract infections, unclassified viral fevers and septicemia. 32 children (10.67%) were found to be severely malnourished and 162 (54%) were anemic.

The pattern of illnesses diagnosed using the IMNCI algorithms was broadly similar to that of the gold standard; however a few prominent differences were observed. In the respiratory diseases category, 63 cases of Severe Pneumonia/Very severe disease were diagnosed. Further, the number of No Pneumonia diagnoses was slightly higher (n=94), than the gold standard equivalent of URI (n=80). Due to inadequate information offered by the parents, 2 cases of dysentery were not picked up in the IMNCI algorithms and were classified under diarrhea with some dehydration. Another major difference was noted in the fever module: the number of malaria cases picked up by applying the IMNCI high malaria risk algorithm was about 10 times as that diagnosed by gold standard (n= 131 vs 16); however the low malaria risk algorithm yielded an under-estimate of malaria morbidity (n=8). Also, 48 cases of very severe febrile disease which needed hospitalization were diagnosed when these algorithms were used. Further, these algorithms resulted in over-diagnosis of 'very low weight for age' (which is equivalent to severe malnutrition) by over 25%. None of the diseases enumerated under 'Others' could be picked up by the use of these algorithms. Using the vertical (split IMNCI) algorithms specific for the presenting symptom reported by the parent/guardian resulted in lower number of diagnoses across all categories of illnesses.

Table – 4. Mean frequency of morbidities in different Methods of evaluations (n = 300)

Parameter	Gold Standard	IMNCI		Vertical (Split IMNCI) algorithm
		High Malaria Risk	Low Malaria Risk#	
Total Number of illnesses	711	795	686	332
Mean number of illnesses	2.37	2.65	2.29	1.11
Standard deviation	1.17	1.29	1.31	0.57

Excluding the classification of "Fever – Malaria Unlikely"

- P < 0.005 ** P = 0.732, *** P<0.001) (using paired t test)
- Gold Standard VS * High malaria risk, ** Low Malaria risk, *** Vertical (split IMNCI) algorithms

711 illnesses were diagnosed as per the 'gold standard', viz, standard procedures of care followed in the hospital (Mean: 2.37, SD: 1.17). When the IMNCI algorithms were used on these children, the high malaria risk algorithm yielded 795 diagnoses and the low malaria risk algorithm yielded 686 diagnoses. However, only 332 diagnoses were made using the vertical (split IMNCI) algorithm. The difference in the mean number of illnesses diagnosed using the high malaria risk algorithm (Mean: 2.65, SD: 1.29) and the gold standard was statistically significant using paired t-test (p<0.005), as was the

difference between vertical algorithms (Mean: 1.11, SD: 0.57) ($p<0.001$) and gold standard. The difference between low malaria risk algorithm (Mean: 2.29. SD: 1.31) was however, not statistically significant ($p=0.548$). The number of children who received more than one diagnosis as per gold standard evaluation was 209 (69.7%). 246 (82%) children received multiple diagnoses using the IMNCI high malaria risk algorithm whereas 193 received multiple diagnoses (64.3%) using the IMNCI low malaria risk algorithm.

In contrast, only 32 (10.7%) children received more than diagnosis, when the vertical (split IMNCI) algorithm was used (Fig.3).

Fig 3. CHILDREN WITH MULTIPLE DIAGNOSES BY DIFFERENT MODES OF EVALUATION

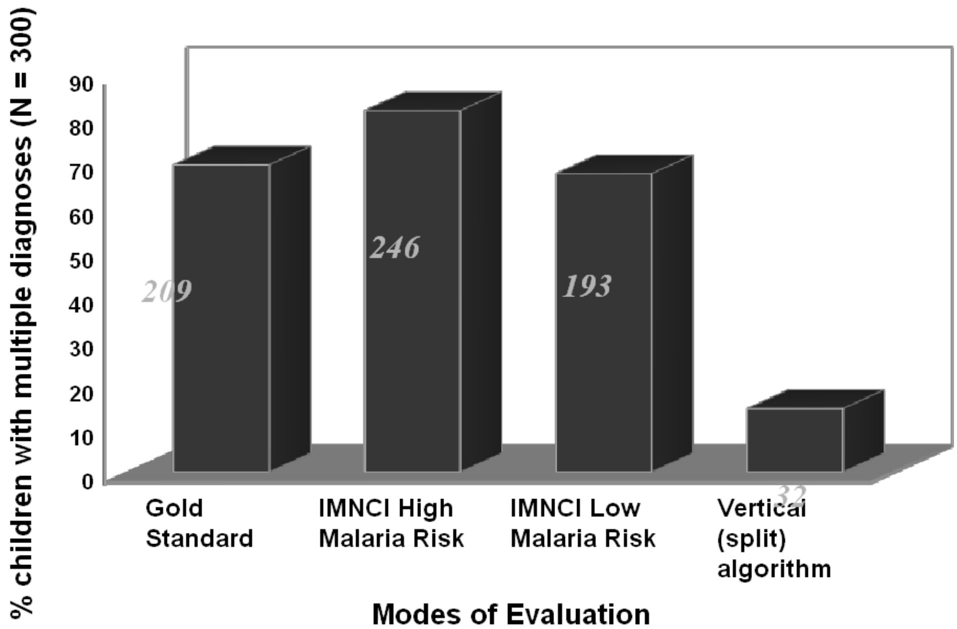


Table – 5. Treatment modalities of the children in study as per gold standard (n = 300)

Treatment modality	No. of Children	% of Total
Hospitalization	143	47.67%
Observation	57	19.00%
Home Treatment	100	33.33%
Total	**300**	**100%**

Of the 300 children, 143 (47.7%) were admitted in the hospital according to the standard treatment and care practices followed in the hospital. 57 (19.0%) were kept under observation in the hospital for a period less than 24 hours while 100 (33.3%) were treated on an outpatient basis, and sent back home immediately with appropriate treatment and counseling (Table –5).

Table – 6. Comparison of referral criteria of IMNCI algorithm with mean frequency of morbidities of study population (n = 300)

Status of referral criteria (IMNCI algorithm)	Number of Children	Mean Number of morbidities	Standard Deviation
Yes	166	2.55	1.28
No	134	2.30	1.32

p = 0.245 (unpaired t test)

On application of the IMNCI algorithms, 166 (55.3%) children met one or more criteria for referral to a hospital. Such children had a greater number of illnesses diagnosed by the gold standard (mean number of morbidities – 2.55 and standard deviation – 1.28), than children without referral criteria (mean number of morbidities – 2.30 and standard deviation – 1.32), however the difference was not statistically significant using paired t test (p = 0.245) (Table – 6).

Table – 7. Role of the referral criteria in predicting the treatment modality (n = 300)

Criteria	Children needed hospitalization		Children kept under observation for not more than 24 hours		Children sent home immediately after initial evaluation		Total	
	No.	%	No.	%	No.	%	No.	%
Children with out any referral criteria	17	12.68	23	17.16	94	70.15	134	100
Children with any one of the referral criteria including General Danger signs	126	75.90	34	20.48	6	3.61	166	100
Children with General Danger signs	87	76.99	20	17.70	6	5.31	113	100

- *χ^2 = 161.07, $p < 0.001$ (Vs children without any referral criteria)
- ** χ^2 = 123.87, $p < 0.001$ (Vs children without any referral criteria)

Over three-fourths (n=126) of children with one or more referral criteria (including the general danger signs) from the IMNCI algorithms were eventually admitted in the hospital by the treating pediatricians. 34 children (20.5%) were kept under observation in the hospital for not more than 24 hours, while 6 of them (3.6%) were advised home-based care after the initial evaluation. When children who presented with general danger signs alone were considered, the changes observed were minimal; the proportion advised admission, observation and home-based care were 76.9%, 17.7% and 5.3%

respectively. In line with these findings, it was noted that abut 70% of children who did not meet any of the IMNCI referral criteria were sent home after the initial evaluation. 17% of such children were placed under observation for a period not exceeding 24 hours, while 12% required admission in the hospital (Table – 7).

Table – 8. Validity of “General Danger Signs” and “Referral Criteria” as a Predictor of hospital admissions / observations

Criteria	Mode of Treatment	Sensitivity %	Specificity %	Positive Predictive Value (PPV) %	Negative Predictive Value (NPV) %	OR (95% CI) (Odds Ratio with 95% confidence interval)
Any of the General Danger Signs positive (n=113)	Hospitalized (n=87)	60.84	83.44	76.99	70.05	7.83 (4.42 – 13.93)
	Hospitalized plus kept under observation (n=107)	53.5	94.00	94.69	50.26	18.03 (7.19 – 47.97)
Any of the Referral Criteria including General danger signs positive (n=166)	Hospitalized (n=126)	88.11	74.52	75.90	87.31	21.68 (11.20 - 42.49)
	Hospitalized plus kept under observation (n=160)	80.00	94.00	96.39	70.15	62.67 (24.23 – 171.78)

The validity of the IMNCI referral criteria in predicting treatment decisions by a pediatrician following usual standards of care was analysed. The accuracy of the four “General Danger Signs” (Convulsions, Lethargy or Unconsciousness, not able to drink or breast-feed and vomits everything) and all ‘Referral Criteria’ outlined in IMNCI algorithms in predicting hospitalization or hospitalization/observation of the child as per gold standard is presented in Table 8. The general danger signs alone had a sensitivity of 60.8% and specificity of 83.4% in predicting hospitalization. The sensitivity increased to 88.1% when the four danger signs were considered along with other referral criteria, though the specificity dropped to 74.5%. The sensitivity of the general danger signs in predicting hospitalization/observation was lower at 53.5% and increased to 80% when considered along with other referral criteria; however the specificity remained unchanged at 94%. In general, the referral criteria had better predictive accuracy for hospitalization/observation than hospitalization alone; positive predictive values ranged from 75.9 to 76.99 for the latter and 94.69 to 96.39 for the former. The odds ratios of being hospitalized was greater when all referral criteria were considered together (OR: 21.68, 95% Confidence Interval: 11.20 - 42.49) than when the general danger signs were considered in isolation (OR: 7.83, 95% Confidence Interval: 4.42 – 13.93). A similar relationship was obtained with hospitalization/observation as the outcome.

Table – 9. Effectiveness of ‘General danger signs’ in predicting severity of illness (n=300)

Number of General danger signs	Modality of treatment as per gold standard		Number of Children
	Hospitalization plus observation	Home treatment	
Nil	40 (21.39%)	147 (78.61%)	187 (100%)
1	68 (94.44%)	4 (5.56%)	72 (100%)
2	36 (94.74%)	2 (5.26%)	38 (100%)
3	3 (100%)	0	3 (100%)

*Chi Square for linear trend: 122.69; P<0.001

113 children enrolled in the study had presented with at least one of the four general danger signs. Of the 72 children who had a single danger sign, 68 (94.4%) were hospitalized or kept under observation, as per gold standard. The proportion of children with two danger signs who got admitted/ hospitalized was only marginally higher (94.74%), but all 3 children who had three danger signs were admitted in the hospital.

The proportion of children who were treated on an ambulatory basis decreased as the number of danger signs increased. More than 78% of children without any danger signs (n=147) were sent home after the initial evaluation, while only about 5% of children with one or two danger signs each were advised home-based care. Thus the number of danger signs showed a linear trend with treatment decisions by the pediatricians; the Chi-square test for linear trend was statistically significant (Table 9)

Table – 10. Therapeutic agreements between gold standard and IMNCI high/low malaria risk algorithms

Match	Admission alone (n= 300)	Admission and observation (n = 300)
Complete match	243 (81%)	254 (84.67%)
Complete mismatch	57 (19%)	46 (15.33%)
Over-diagnosis	40 (13.33%)	6 (2%)
Under-diagnosis	17 (5.67%)	40 (13.33%)
Kappa statistic (95% Confidence Interval)	0.622 (0.535 to 0.709)	0.682 (0.600 to 0.764)

The therapeutic agreement of the IMNCI algorithms (on basis of meeting referral criteria) with the gold standard treatment modality is presented in Table 10. Of the 300 children in the study, the IMNCI algorithm concurred with the decision by pediatrician to hospitalize the child in 81% cases (n=243) and completely differed in the remaining 57 children. Of these 57 children, 40 (13.3%) had at least one of the referral criteria positive, but were not hospitalized (over-diagnosis) and 17 (5.7%) had no referral criteria but ended up being hospitalized (under-diagnosis). When hospitalization was considered along with observation not exceeding 24 hours as the therapeutic decision by the pediatrician, concurrence increased to 84.7% and mismatch decreased to 15.3%; however most cases of mismatch comprised of children without any of the referral criteria being hospitalized/kept under observation (under-diagnosis, n= 40, 13.3%) than children with referral criteria who were sent home after evaluation (over-diagnosis, n=6, 2%) (Table 10).

The Kappa statistic was also calculated to study agreement between IMNCI algorithms and gold standard. Kappa value was 0.622 (95% Confidence Interval: 0.535 to 0.709) for hospitalization and 0.682 (95% Confidence Interval: 0.600 to 0.764) for hospitalization / observation. This indicates that the two methods enjoyed good agreement between themselves.

Table – 11. Analysis of diagnostic and therapeutic agreements between 'Gold Standard' and IMNCI and Vertical (Split IMNCI) algorithms (n = 300)

Parameter	IMNCI Algorithm		Vertical (Split IMNCI) algorithm
	High Malaria Risk No.(%)	Low Malaria Risk No. (%)	
Total Agreement	239 (79.67)	258 (86.0)	169 (56.33)
Partial Agreement	38 (12.67)	24 (8.0)	34 (11.33)
Total Disagreement	23 (7.67)	18 (6.0)	97 (32.33)
Over-diagnoses	117 (39.00)	45 (15.0)	17 (5.67)
Under-diagnoses	62 (20.67)	66 (22.0)	218 (72.67)

Upon assessing the therapeutic and diagnostic agreement of the IMNCI algorithms with the gold standard, it was seen that total agreement was highest for the IMNCI low malaria risk algorithm and lowest for the vertical (split IMNCI) algorithmic approach. Total agreement was considered when the child's classification as per the IMNCI referral criteria matched with the modality of treatment offered (hospitalization/ observation / home treatment) or when all diagnoses made using the IMNCI algorithms matched with the corresponding gold standard diagnoses. Total agreement with gold standard was seen in 258 children (86%) when the low malaria risk algorithm was used and 239 children (79.7%) when the high malaria risk algorithm was used. Total agreement was seen only in 169 children (56.3%) when the vertical (split) algorithms were used.

Total disagreement was considered when none of the diagnoses made using the IMNCI algorithms matched with the gold standard diagnoses. Total disagreement was highest for vertical (split) approach (32.3%) and lowest for low malaria risk algorithm (6%). Total disagreement was about 7.7% for the high malaria risk algorithm.

When some but not all of the IMNCI diagnoses matched with the gold standard diagnoses, it was considered as Partial agreement. Partial agreement was lowest for the low malaria risk IMNCI algorithm at 8%. The high malaria risk algorithm and vertical (split) approach yielded comparable estimates of partial agreement at 12.7% and 11.3% respectively.

Compared to the gold standard, the vertical (split) algorithmic approach made the least number of over-diagnoses (17, 5.7%). The largest extent of over-diagnoses was seen with the high malaria risk algorithm, with 39% of children (n=117) receiving more diagnoses than the gold standard. This was mainly due to the classification of all fevers as malaria under this algorithm.

The low malaria risk algorithm fared better in this regard, with 15% children receiving over-diagnosis.

In contrast, the vertical (split) approach resulted in a substantial number of children receiving lesser diagnoses than the gold standard; 72.7% children were under-diagnosed. Under-diagnosis was quite low with the low malaria risk algorithm (22%) and with the high malaria risk algorithm (20.7%) (Table 11).

Table – 12. Comparison of diagnostic and therapeutic agreements between the study population from emergency room and out patient department

Agreement	Emergency Room visits (n=131)			OPD Visits (n=169)		
	IMNCI Algorithm		Vertical (split IMNCI) Algorithm No.(%)	IMNCI Algorithm		Vertical (split IMNCI) Algorithm No.(%)
	High Malaria Risk No.(%)	Low Malaria Risk No. (%)		High Malaria Risk No.(%)	Low Malaria Risk No.(%)	
Total Agreement	117 (89.31)	121 (92.37)	58 (44.27)	122 (72.19)	137 (81.07)	111 (65.68)
Partial Agreement	6 (4.58)	6 (4.58)	12 (9.16)	32 (18.93)	17 (10.06)	22 (13.02)
Total Disagreement	8 (6.11)	4 (3.05)	57 (43.51)	15 (8.88)	14 (8.28)	40 (23.67)
Over-diagnoses	32 (24.43)	18 (13.74)	12 (9.16)	85 (50.30)	27 (15.98)	5 (2.96)
Under-diagnosis	34 (25.95)	42 (32.06)	96 (73.28)	28 (16.57)	24 (14.20)	122 (72.19)

Diagnostic/therapeutic agreements stratified by the mode of recruitment of the child are presented in Table 12. Children recruited from the OPD and those from the emergency room visits were compared with regards to the agreements between gold standard and IMNCI algorithmic approaches. It was seen that the total agreement was higher for the high and low malaria risk algorithms in the children recruited from emergency room visits (89.3% and 92.4% respectively) than those from the OPD (72.2% and 81.1% respectively) as also the entire study sample (79.7% and 86% respectively). Total disagreement was also lower for both algorithms in the emergency room children (7.7% and 6% respectively) than those recruited from OPD (8.9% and 8.3% respectively). Partial agreement was also seen to be lower among children recruited from emergency room visits than from OPD visits. For the vertical (split) algorithmic approach, total disagreement was higher and total agreement lower among children enrolled during emergency room visits (43.5% and 44.3% respectively) than those enrolled during OPD visits (23.7% and 65.7% respectively) or that in the entire study sample (32.3% and 56.3% respectively).

The low malaria risk IMNCI algorithms yielded comparable proportion of over-diagnoses in both categories of subjects (13.7% and 15.9% respectively), while under-diagnoses were far more common among emergency room recruits (32.1%) than OPD recruits (14.2%). The proportion of over-diagnoses in the OPD enrolled children was almost twice that in the emergency room enrolled children (50.3% Vs 24.4%) using the high malaria risk IMNCI algorithm while under-diagnosis was greater in the latter group (36.6%) than the latter (27.2%). The performance of the vertical (split) algorithms was not appreciably different in the emergency room and the OPD in terms of proportion of children being under- or over-diagnosed.

Thus it can be seen that with respect to diagnostic/therapeutic agreement with the gold standard, the low malaria risk IMNCI algorithm scores highest. It has the least number of total disagreements and the most number of total agreements and also has acceptable levels of under-diagnoses and over-diagnoses across the study sample and also in the settings of the emergency room and the OPD. The high malaria risk algorithm suffers due to higher number of over-diagnoses due to classification of all fevers as malaria; while the vertical (split) approach is associated with unacceptable levels of under-diagnosis.

Table – 13 Immunization status of the study population (n=300)

Immunization status	Children recruited in OPD	Children recruited in ER	Total No. of children
Immunized Appropriately for Age	140 (46.67%)	113 (37.67%)	253 (84.33%)
Not Immunized Appropriately for Age	29 (9.67%)	18 (6.00%)	47 (16.67%)
Total Number of Children	169 (56.33%)	131 (43.67%)	300 (100%)

47 children (16.7%) enrolled in the study were found to be not appropriately immunized for age and were picked up by the IMNCI algorithm. Immunization counseling was offered to all parents or guardians of children who participated in the study.

DISCUSSION

Table – 14. Comparison of co-existence of illnesses among various studies

Study	Person applied IMNCI algorithm	Setting	Mean number of Illnesses	Percentage of children with multiple (≥ 2) diagnoses
Kolstad., et al.[18] (Uganda)	Trained health worker	Out Patient department	2	69.0%
Shah D., et al.[13] (Delhi)	Pediatrician	Out Patient department and emergency room	2.1	66.5%
Present Study	Pediatrician	Out Patient department and emergency room	2.39	69.60%

The chief objective of the present study was to assess the utility of the IMNCI algorithms in a South Indian setting. The utility of the IMNCI approach can be measured in terms of the need for adopting an integrated approach, the applicability of the algorithm in our setting and the validity of the algorithms in predicting diagnosis and/or treatment.

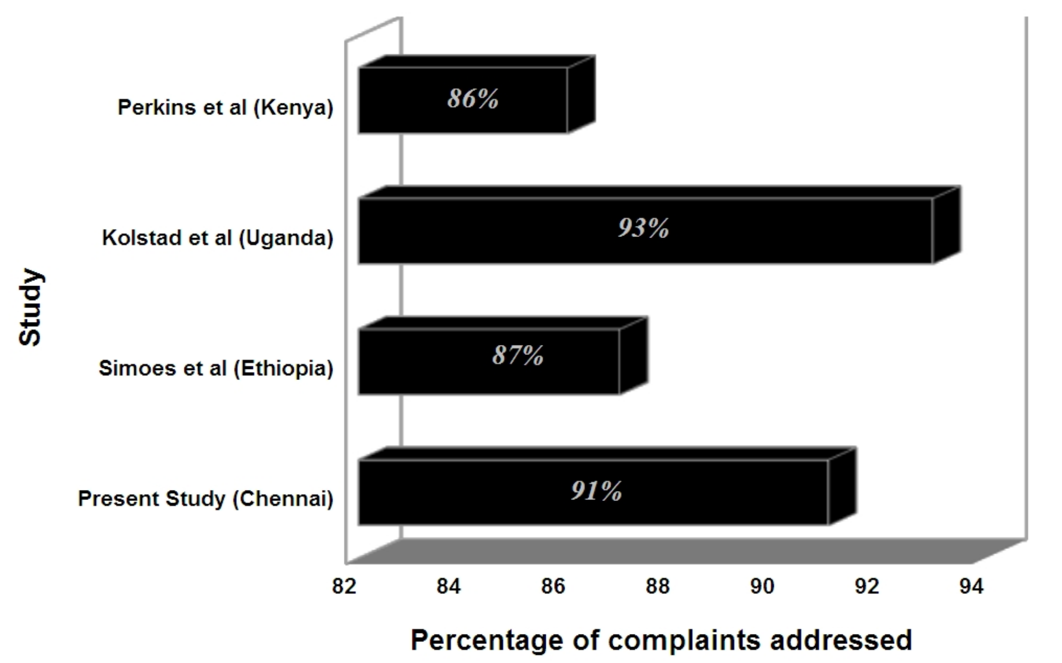
The chief argument in favour of adoption of an integrated approach to the management of childhood illnesses is the co-existence of more than one illness in a sick child. Such overlap renders a single diagnosis impossible and inappropriate for most sick children and also complicates therapeutic modalities. In the present study, more than two thirds of the participating children (69.7%) were found to have multiple diagnoses according to the standard diagnostic procedures followed in the hospital ('gold standard'). This finding is in agreement with reports of more than one illness per child that have emerged from other settings such as Uganda, Ludhiana and New Delhi and reiterates the importance of adopting an integrated approach to the management of sick children[13,18,26]. The mean number of illnesses diagnosed per child was 2.37 in the current study, which was higher than what has been previously reported in India; 1.75 in Ludhiana and 2.1 in New Delhi[13,26]. This might be due to the higher number of children who were malnourished or anemic in this study (38% and 54% respectively) as most children attending the hospital where the study was conducted belong to the lower socioeconomic strata.

Previous studies have shown that the more seriously ill a child is, the more number of illnesses he is likely to have. A higher number of illnesses was recorded in children who met any of the IMNCI referral criteria in the current study (2.55) which is similar to that reported by Shah et al in New Delhi (2.5); however much higher numbers of morbidity was recorded here than in New Delhi even among children without a referral criterion (2.30 and 1.6 per child respectively) [13]. While this could be reflective of the overall higher levels of morbidity in the present study sample than previously reported, it brings to light the fact that even children with mild illnesses could have multiple problems. Thus multiple illnesses seem to be the rule rather than the exception in child health and management of sick children by health workers trained in single disease specific programmes may lead to under-diagnosis and not initiating treatment for associated and potentially life-threatening conditions[4]. So it is essential that health workers in the community and hospital be trained to recognize all morbidities in a child and institute timely, appropriate treatment. Table 14 gives a comparative overview of this underlying rationale for the IMNCI from different settings.

An important metric of the local applicability of the IMNCI algorithm is its ability to address commonly encountered complaints in sick children. The proportion of presenting complaints that were addressed by the IMNCI algorithms in various studies from Africa and Asia has been reported to be around 90% [15,16,18]. In the present study too, the IMNCI algorithm was able to address over 90% of the complaints voiced by arents/guardians of children. Cough or difficult breathing, fever and diarrhea constituted over three-fourths of all symptoms reported in this study and consequently were covered adequately by IMNCI algorithm, similar to studies from Kenya, Gambia, Uganda and Ethiopia[15,16,17,18,20]. Respiratory infections and diarrheal illnesses along with other febrile illnesses are the major killers in the under five age group and it is reassuring that the IMNCI algorithm covers these deadly diseases.

All previous studies have indicated that a small proportion of complaints were not addressed by the algorithm. Early in the development of the IMNCI algorithm, Weber et al. had reported from Gambia that vomiting and poor feeding, two symptoms commonly encountered in pediatric practice, were not included in the IMNCI algorithm[17]. This led to a revision of the IMNCI algorithm when poor feeding and vomiting everything were added in to the algorithm as general danger signs. Other common complaints such as skin

Fig.4 COMPARISON OF EFFECTIVENESS OF IMNCI ALGORITHM IN ADDRESSING PRESENTING COMPLAINTS



problems and pain abdomen have been reported in other studies as being not addressed by IMNCI algorithm[15,18]. Prominent among those complaints which were not covered by the IMNCI algorithm in the present study were worms in stools and perianal itching, skin problems and abdominal problems. Inclusion of more complaints in the IMNCI algorithm is likely to make it unwieldy for use in the field setting and may lead to oversight of more common problems by the health worker that can endanger the life of the child, if left untreated. Considering this, it is desirable that the algorithm be kept simple and efforts made for training the field workers to elicit other symptoms/signs from the parents/guardians/children under the "Assess other problems" section in the IMNCI algorithm.

The priority in low resource settings is early recognition of serious illness, so that such children can be referred for hospital care. Thus the referral criteria form the backbone of the IMNCI approach. Before advocating for wider adoption and use, the validity of the referral criteria in predicting serious illness has to be verified locally. High sensitivity and positive predictive value are imperative for any screening tool to avoid individuals with the disease getting left out. At the same time, the test or tool should have specificity in an acceptable range so that false positives and hence wasteful expenditures are minimized.

About 55% of children met one or more of the IMNCI referral criteria in the present study. This frequency is in line with 47 to 53% referral rates reported in studies from the Indian sub-continent, but much higher than the initial reports from IMNCI evaluation studies conducted in Africa[13,14,26]. In these studies from Kenya, Gambia, Uganda and Ethiopia the referral rates ranged from 7% to 28%[15,16,17,18,20]. The low referral rates seen in the earlier African studies has been attributed to the enrollment of study subjects only from the out-patient department, where seriously illness children are less likely to be present. In the recent studies in India and Bangladesh subjects have been both from the out-patient department and the emergency rooms and higher rates of referral have been evident.

The sensitivity of the algorithm in recognizing severely ill children who need in- hospital care through the referral criteria is the most important measure of the utility of the IMNCI approach. This ranged from 41% to 84% in studies from Africa and 81% to 86% in studies from India and Bangladesh. Specificity of the tool ranged from 64% to 74% in the latter, and from 79% to 98% in the former. Positive predictive values ranged from 55% to 71%[13, 14,15,16,17,18,20]. A recently published study from Ludhiana, India by Kundra et al reported excellent sensitivity and specificity at 99.3% and 97.3% respectively[26]. The sensitivity, specificity and positive predictive value for predicting hospitalization in the present study were 88.1%, 74.5% and 75.9% respectively (Table 15).

Table – 15. Comparison of effectiveness of Referral Criteria

Study	IMNCI algorithm assessed by	N	Setting	% cases with referral criteria	Sensitivity %	Specificity %	PPV %	NPV %	OR (95% CI)
Paxton., et al[20] (Kenya)	Trained Health Worker	2799	Out Patient Department	28	46	79			3.2 (2.7-3.9)
Weber., et al.[17] (Gambia)		440	Out Patient Department	14	45	93	59		11.3(5.9-21.5)
Perkin.,et al.[16] (Uganda)		1794	Out Patient Department	14	42	94			12.2(8.9 – 16.7)
Kolstad., et al.[18] (Uganda)		1226	Out Patient Department	16	41	91			7.0(5.0-9.8)
Simoes.,et al.[15] Ethiopia		449	Out Patient Department	7	66	98	68		77.7(27.1-231.2)
Simoes.,et al.[15] Ethiopia	Pediatrician	449	Out Patient Department	9 (8.5%)	84	97	71		199.3 (58.3-737.2)
Kalter., et al.[14] (Bangladesh)		668	Out Patient Department + Emergency Room	53	86	64	55		11.2(7.2-17.6)
Shah D., et al.[13] (Delhi)		203	Out Patient Department and Emergency Room	47	H – 81 H+ 0 – 69	74 85	66 88	86 65	11.7(5.6-24.1) 12.7 (5.9-28.1)
Kundra S et al.[26] (Ludhiana)		309	Out Patient Department and Emergency Room	47.8	99.3	97.3			
Present study (Chennai)		300	Out Patient Department and Emergency Room	166 (55.33%)	H – 88.1 H+O 80.0	74.5 94.0	75.9 96.4	87.3 70.2	21.7 (11.2-42.5) 62.7 (24.2-171.8

H = Hospitalization, H+O = Hospitalization + Observation, PPV = Positive Predictive Value, NPV = Negative Predictive Value, OR (95% CI) = Odds Ratio (95% Confidence Interval)

The chief differences between the African and Asian studies were in the type of recruitment and the person administering the algorithm. As seen earlier, in all African studies, children were recruited from the out-patient department whereas in India and Bangladesh, children attending emergency rooms were also included. This difference in recruitment procedures could have impacted on the prevalence of serious illness and hence the children meeting the IMNCI referral criteria, thus influencing the positive predictive values of the algorithm, as predictive values are known to be dependent on the underlying prevalence of the disease in any setting. However, this could not alter sensitivity or specificity, which are intrinsic traits of a given test itself, and are influenced only by how well the test is performed in different settings and not by extrinsic factors such as prevalence. Hence, the chief reason behind the differing sensitivities of the algorithm in the African and Asian studies is due to the differing skills of the individuals administering the tool. In the African studies, all assessments were done by health workers, while the Asian studies had pediatricians/doctors performing the assessments. Thus, the Asian and African studies depict two different scenarios; the Asian studies portray an idealized setting where the health worker has all the knowledge and skills akin to a medical professional, and the African studies as to what would happen in actual settings, when peripheral health workers with limited knowledge use the algorithms.

Health workers in the community, the intended users of the IMNCI approach, have been shown to possess limited knowledge about disease symptomatology and their recognition of clinical signs such as chest in-drawing or pedal edema can be inaccurate. Further, these workers may have problems in comprehension and application of an algorithmic approach. Hence their use of the IMNCI algorithm will be less effective, leading to sub-optimal validity. This underscores the importance of training field workers in the algorithms and clinical skills so that the full utility of the tool can be realized. In a study done in Ethiopia, the delivery of the correct treatment as per IMNCI algorithm by a health worker increased from 69% in the first week to 88% in the third week after training was completed. Follow-up interviews with health workers one year after training revealed that it took three months of constant working with the charts for them to get familiarized with the algorithms[15]. Hence adequate emphasis on training of the health workers and supportive supervision or mentoring after training is essential to improve their performance over time.

In the current study, the sensitivity decreased to 80%, but the specificity rose up to 94% when the referral criteria were tested as predictors of hospitalization or observation for less than 24 hours in the hospital. Pediatricians resort to such short time observations if they are unsure about the optimal modality of treatment for a child at the first instance of clinical evaluation. Such children are likely more ill than children who are sent back home after initial evaluation and hence it is important that such children get referred to a hospital.

The studies from India on IMNCI have all been conducted in tertiary medical care centres, and have estimated the degree of agreement between IMNCI algorithm approach and usual standards of care practiced at the hospital[13,25,26]. In the current study, total diagnostic/therapeutic agreement with gold standard was highest for the low malaria risk algorithm in the present study and lowest with the vertical (split) algorithm, which also suffered the largest proportion of total disagreements and under-diagnoses among all three algorithms. The vertical (split) algorithm is narrow-minded in its approach, focusing only on the presenting complaint and hence will miss out co-morbidities in the child. The high malaria risk algorithm had the highest proportion of over-diagnosis, owing to classification of all children with fever as having malaria. Similar findings have been reported in the study by Shah et al from New Delhi and Kundra et al in Ludhiana[13,26].

Table – 16. Comparison of Diagnostic and Therapeutic Agreements

<table>
<tr><th>Study</th><th>Type of Algorithm</th><th>Total Agreement %</th><th>Partial Agreement %</th><th>Total Disagreement %</th><th>Over-diagnosis %</th><th>Under-diagnosis %</th></tr>
<tr><td rowspan="3">Shah.,et al.[8] (Delhi)</td><td>High Malaria Risk IMNCI</td><td>54.2</td><td colspan="2">45.8</td><td>29.6</td><td>24.6</td></tr>
<tr><td>Low Malaria Risk IMNCI</td><td>63.5</td><td>21.2</td><td>15.3</td><td>19.7</td><td>26.1</td></tr>
<tr><td>Vertical (Split IMNCI)</td><td>45.8</td><td>25.1</td><td>29.1</td><td>15.8</td><td>56.6</td></tr>
<tr><td rowspan="3">Present Study</td><td>High Malaria Risk IMNCI</td><td>79.7</td><td>12.7</td><td>7.7</td><td>39.0</td><td>20.7</td></tr>
<tr><td>Low Malaria Risk IMNCI</td><td>86.0</td><td>8.00</td><td>6.0</td><td>15.0</td><td>22.0</td></tr>
<tr><td>Vertical (Split IMNCI)</td><td>56.3</td><td>11.3</td><td>32.3</td><td>5.7</td><td>72.7</td></tr>
</table>

The IMNCI algorithms also had dissonance with the gold standard diagnoses in the cough or difficult breathing category, where many children with bronchial asthma, bronchiolitis, empyema or tuberculosis were classified as having pneumonia, severe pneumonia or URI. This makes the former set of conditions to be under-diagnosed, and pneumonia/respiratory infection to be over-diagnosed. However even with incorrect diagnoses, all cases of bronchiolitis, severe asthma and empyema had met the IMNCI criteria for referral and hence would have been referred to a doctor. But it is not so with cases of bronchial asthma who were misclassified as pneumonia or URI and thus would have received inappropriate treatment (Table 16).

IMNCI algorithm also resulted in slight over-diagnosis of anemia and classification of a few children with grade II malnutrition as being severely malnourished (very low weight for age). The former is due to reliance on palmar pallor to classify anemia. The use of weight for age rather than weight for height curves to classify malnutrition may result in such discrepancies as noted in this study; however weight for age curves are much simpler to use in the field, where measurement of height or length of the child may become problematic.

Adoption of IMNCI strategy also provides for the detection of children who have not been immunized adequately for their age. This is a common aspect that may be overlooked by over-burdened health staff attending to sick children in the community and the algorithm provides a reminder in this regard so that missed opportunities for immunization may be avoided. In the current study around 17% children were found to be not appropriately immunized for age and were provided vaccines as deemed necessary. Immunization counseling was offered to all parents and guardians.

Further improvements in IMNCI algorithm are needed in the cough/difficult breathing category to avoid under-diagnosis of bronchial asthma (being misclassified as URI or pneumonia) and in the fever category to avoid over or under-diagnosis of malaria and other febrile illnesses through incorporation of simple diagnostics such as rapid antigen tests, QBC etc, if necessary. The study area being a malaria non-endemic zone, the low malaria risk algorithm seems most suited for evaluation of a child with fever, however it may under-diagnose malaria. But in high malaria zones, it is considered safe to over-diagnose a child with malaria and offer treatment. Similar findings have been reported from New Delhi[13].

The IMNCI algorithm is a tool meant to be used in the community and low resource health care facilities, by primary health care workers. Studies such as the present one which are done in tertiary care centres hence are of limited utility in assessing the performance of the algorithms in the field. The case-mix seen in tertiary centres is entirely different from what is seen in a rural health centre and hence patterns of diagnostic/therapeutic agreement estimated in these studies may not be replicated in field studies. Further, such hospital based studies are often conducted by pediatricians or physicians with vastly different skill sets compared to a peripheral health worker. Hence, as noted before, the measures of validity reported in the Indian studies are not reflective of what may be obtained in primary care settings and estimates reported in the African studies seem more plausible.

Many studies from African countries have also assessed the performance of the health worker and based on their observations, some modifications have been done in the IMNCI algorithm to improve its utility. A study from United Republic of Tanzania, assessed the performance of three types of health workers (medical assistants, rural medical aides and MCH aides) after adequate training and found that all three groups overall were able to assess, classify, and treat most sick children and most of them were able to provide adequate counselling[19]. Studies done in Kenya and Uganda had compared the drug costs incurred with standard treatment by physicians against projected costs upon using the IMNCI algorithm and found that adoption of the IMNCI approach is associated with a cost advantage[21,22].

It must be noted that despite a decade since its adoption, few serious attempts at evaluation of the IMNCI strategy have been taken up in india. Validation studies should be taken up in sub-centres and primary health centres across the country to identify if the algorithms need further adaptation to suit local circumstances. Further a nationwide assessment of the implementation of the strategy is necessary to identify systemic bottlenecks including the supply of IMNCI cards to health workers, availability of commonly prescribed drugs and training of health workers.

CONCLUSION

The present study is broadly in agreement with previously conducted research on utility of IMNCI approach. It can be concluded that adoption of IMNCI is desirable for the following reasons:

1. Multiple diagnoses are the rule than an exception in under five sick children
2. Hence vertical, disease specific algorithms are inappropriate in the evaluation and management of a sick child. Integrated approaches must be preferred.
3. The IMNCI algorithm can address most complaints that sick children present with
4. When implemented by health workers with appropriate training, the referral criteria of IMNCI are fairly good predictors of serious illness which requires medical attention
5. Diagnostic concordance of the low malaria risk IMNCI algorithm with the gold standard is good
6. IMNCI also ensures prompt assessment of nutritional and immunization status, which may be often missed by health workers during evaluation of a sick child. Thus it provides opportunities to foster better growth and development of the child through preventive care
7. Further refinement of the algorithm (for ex: to eliminate difficulties in diagnosing bronchial asthma and malaria) can be considered, after

careful appraisal of the performance of the tool in actual field settings where it is intended to be used.

BIBLIOGRAPHY

1. Black RE, Morris SS, Bryce J. Where and why are 10 million children dying every year? Lancet 2003; 361: 2226–34
2. Jones G, Steketee RW, Black RE, Bhutta ZA, Morris SS and the Bellagio Child Survival Study Group. How many child deaths can we prevent this year? Lancet 2003; 362: 65–71
3. Gove S. Integrated management of childhood illness by outpatient health workers : Technical basis and overview. Bull WHO 1997; 75 (Suppl 1) : 7-24.
4. World Health organization. Integrated management of the sick Child. Bull WHO 1995; 73 (6) : 735-740.
5. Patwari AK, Raina N. Integrated Management of Childhood Illness (IMCI): A Robust strategy. Indian J Pediatr 2002; 69(1) : 41-48.
6. Costello A. Is India Ready for Integrated Management of Childhood Illness strategy? Indian Pediatr 1999; 36; 759-762.
7. Gove S, Tamburlini G, Molyneux E, Whitesell P, Campbell H. Development and technical basis of simplified guidelines for emergency triage assessment and treatment in developing countries. Arch Dis child 1999; 81 : 473-477.
8. Paul VK. Child Health programs. In : Ghai Essential Pediatrics, 5th Edn, Eds, OPGhai, Piyush Gupta, VK Paul, Interprint, New Delhi 2000; pp,519-523.

9. Vijay Kumar. Integrated Management of Childhood Illnesses. In : Frontiers in Social Pediatrics, 1st Edn, Eds AK Patwari, Sachdev HPS, Jaypee brothers, New Delhi 1998; pp,409-422.
10. World Development Report 1993: Investing in health. The World Bank, Washington DC, 1993.

Accessed on 13th November, 2011 at http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/1993/06/01/000009265_3970716142319/Rendered/PDF/multi0page.pdf
11. Claeson M, Gillespie D, Mshinda H, Troedsson H, Victoria CG; Bellagio Study Group on Child Survival. Knowledge into action for child survival. Lancet. 2003 Jul 26;362(9380):323-7
12. Bryce J, Victora CG, Habicht JP, Black RE, Scherpbier RW; MCE-IMCI Technical Advisors. Programmatic pathways to child survival: results of a multi-country evaluation of Integrated Management of Childhood Illness. Health Policy Plan. 2005 Dec;20 Suppl 1:i5-i17.
13. Shah D, Sachdev HPS. Evaluation of the WHO/UNICEF Algorithm for Integrated Management of Childhood illness between Two months and Five year. India Pediatr 1998; 36:767-777.
14. Kalter HD, Schillinger JA, Hossain M, et al. Identifying sick children requiring referral to hospital in Bangladesh. Bull WHO 1997;75 (Suppl 1) : 65-75.
15. Simoes EAF, Desta T, Tessema T, Gerbresellassie T, Dagnew M, Gove S. Performance of health workers after training in integrated

management of childhood illness in Gondar, Ethiopia. Bull WHO 1997; 75 (Suppl 1) : 43-53.

16. Perkins BA, Zucker JR, Otieno J, et al. Evaluation of an algorithm for integrated management of childhood illness in an area of Kenya with high malaria transmission. Bull WHO 1997; 75 (Suppl 1) : 33-42.
17. Weber MW, Mulholland EK, Jaffar S, Troedsson H, Gove S, Greenwood BM. Evaluation of an algorithm for the integrated management of childhood illness in an area with seasonal malaria in Gambia. Bull WHO 1997; 75 (suppl 1) : 25-32.
18. Kolstad PR, Burnham G, Kalter HD, Kenya-Mugisha N, Black RE. The integrated management of childhood illness in western Uganda. Bull WHO 1997; 75 (suppl 1) : 77-85.
19. World Health Organization. Integrated Management of Childhood Illness : Field test of the WHO/UNICEF training course in Arusha, United Republic of Tanzania. Bull WHO 1997; 75 (Suppl 1) : 55-64.
20. Paxton LA, Rdd Steketee RW, Otieno JO, Nahlen B. An evaluation of clinical indicators for severe paediatric illness. Bull WHO 1996; 74(6): 613-618.
21. Kolstad PR, Burnham G, Kalter HD, Kenya-Mugisha N, Black RE. Potential implications of the integrated management of childhood illness (IMCI) for hospital referral and pharmaceutical usage in western Uganda. Tropical Medicine and International Health 1998; 3(9) : 691-699.

22. Boulanger LL, Lee LA, Odhacha A. Treatment in Kenyan rural health facilities : projected drug costs using the WHO-UNICEF integrated management of childhood illness (IMCI) guidelines. Bull WHO 1999; 77(10); 852-858.

23. Factor SH, Schillinger JA, Kalter HD, et al. Diagnosis and management of febrile children using the WHO/UNICEF guidelines for IMCI in Dhaka, Bangladesh. Bull WHO 2001 ; 79(2) : 1096 – 1105.

24. Kahigwa E, Schellenberg D, Armstrong Schellenberg J, Aponte JJ, Alonso PL, Menendez C. Inter-observer variation in the assessment of clinical signs in sick Tanzanian children. Trans R Soc Trop Med Hyg 2002 ; 96: 162-166.

25. Jain R, Awasthi S, Awasthi A. IMCI Approach in tertiary hospitals in India. Indian J Pediatr 2009; 76 (7) : 725-727.

26. Kundra S, Singh T, Chhatwal J. Utility of Indian Adaptation of Integrated Management of Childhood Illness (IMCI) Algorithm. Indian J Pediatr 2008; 75 (8) : 781-785.

27. Gupta R, Sachdev HPS, Shah D. Evaluation of the WHO/UNICEF Algorithm for integrated management of childhood illness between the ages of one week to two months. Indian Pediatrics 2000;37: 383-390.

28. Kaur S, Singh V, Dutta AK, Chandra J. Validation of IMNCI Algorithm for Young Infants (0-2 months) in India. Indian Pediatrics 2011; 48:955-960

ANNEXURES

IMNCI ALGORITHM

MANAGEMENT OF THE SICK YOUNG INFANT AGE UP TO 2 MONTHS

Name: ______________________ Age: _____ Weight: _____kg Temperature: _______°C **Date:**

ASK: What are the infant's problems? ______________________ Initial visit? _______ Follow-up Visit? _______

ASSESS (Circle all signs present) **CLASSIFY**

ASSESS	CLASSIFY
CHECK FOR POSSIBLE BACTERIAL INFECTION / JAUNDICE • Has the infant had convulsions? • Count the breaths in one minute._____ breaths per minute Repeat if elevated ________ Fast breathing? • Look for severe chest indrawing. • Look for nasal flaring. • Look and listen for grunting. • Look and feel for bulging fontanelle. • Look for pus draining from the ear. • Look at the umbilicus. Is it red or draining pus? • Look for skin pustules. Are there 10 or more pustules or a big boil? • Measure axillary temperature (If not possible, feel for fever or low body temperature): - 37.5°C or more (or feels hot)? - Less than 35.5°C ? - Less than 36.5°C but above 35.4°C (or feels could to touch)? • See if young infant is lethargic or unconscious • Look at young infant's movements.. Less than normal? • Look for jaundice. Are the palms and soles yellow?	
DOES THE YOUNG INFANT HAVE DIARRHOEA? Yes ___ No ___ • For how long? ____ Days. • Is there blood in the stool? • Look at the young infant's general condition. Is the infant: - Lethargic or unconscious? - Restless and irritable? • Look for sunken eyes. • Pinch the skin of the abdomen. Does it go back: - Very slowly (longer than 2 seconds)? - Slowly	
THEN CHECK FOR FEEDING PROBLEM & MALNUTRITION • Is there any difficulty feeding? Yee __ No ___ Determine weight for age. Very low ___ Low___ Not Low ___ • Is the infant breastfed? Yes _____ No___ If Yes, how many times in 24 hours?____ times • Does the infant usually receive any other foods or drinks? Yes ___ No ___ If Yes, how often? • What do you use to feed the infant? **If the infant has any difficulty feeding, is feeding less than 8 times in 24 hours, is taking any other food or drinks, or is low weight for age AND has no indications to refer urgently to hospital:** **ASSESS BREASTFEEDING:** • Has the infant breastfed in the previous hour? If infant has not fed in the previous hour, ask the mother to put her infant to the breast. Observe the breastfeed for 4 minutes. • Is the infant able to attach? To check attachment, look for: - Chin touching breast Yes ___ No ___ - Mouth wide open Yes _____ No ___ - Lower lip turned outward Yes ____ No ___ - More areola above than below the mouth Yes___ No ___ *no attachment at all* *not well attached* *good attachment* • Is the infant suckling effectively (that is, slow deep sucks, sometimes pausing)? *not suckling at all* *not suckling effectively* *suckling effectively* • Look for ulcers or white patches in the mouth (thrush). • Does the mother have pain while brteastfeeding? If yes, than look for: - Flat or inverted nipples, or sore nipples - Engorged breasts or breast abscess	
CHECK THE YOUNG INFANT'S IMMUNIZATION STATUS Circle immunizations needed today. BCG DPT 1 OPV 0 OPV 1 HEP-B 1	Return for next immunization on: ______ (Date)
ASSESS OTHER PROBLEMS:	

PAEDIATRICIAN CHART

UNIT: OP NO: DATE: TIME:

C/O

ADMITTED OR NOT:

IF NOT (OP)

General Examination:

Systemic Examination:

CVS:

RS:

P/A:

CNS:

Investigations (if any):

Diagnosis:

Follow up:

IF ADMITTED(IP)

WARD: IP NO: DATE OF ADMISSION:

DATE OF DISCHARGE: DURATION OF HOSTITAL STAY:

DIAGNOSIS:

General Examination:

Systemic Examination:

CVS:

RS:

P/A:

CNS:

Investigations :

CBC: *P.S:*

URINE R/E: *CSF Analysis:*

URINE C&S:

BLOOD CULTURE:

CHEST X- RAY:

OTHERS:

OUTCOME:

FOLLOW UP:

PATIENT INFORMATION SHEET

The evaluation of IMNCI algorithm for children aged between 2 months to 5 years in a tertiary referral centre

(To be read to caretakers in the presence of witness)

More than ten million children die every year even before they reach their fifth birthday. 7 in 10 deaths are due to acute respiratory infections, diarrhea, malaria, measles and malnutrition. 3 in 4 episodes of childhood illness are caused by one of these five conditions.

So WHO and UNICEF launched the global initiative of IMCI in 1992. This strategy has been expanded in India to include all neonates and renamed as **"Integrated management of neonatal and childhood illness" (IMNCI).**

It is essential to study the performance of the algorithms in diverse settings to guide local adaptability. This study would be the first to assess utility of IMNCI protocols in South India/Tamilnadu.

So the aim of the study is to evaluate the utility of IMNCI algorithm in predicting illness, hospitalization and management of children aged between 2 months to 5 years.

How is study being done?

Each recruited child will be assessed by the investigator using a detailed questionnaire that will include sociodemographic characteristics, history and clinical examination. The proforma will include all signs and symptoms which are included in the IMNCI algorithms, in the same order.

Once the IMNCI assessment by the investigator is complete, the children will be seen by a physician (Assistant professors of the treating unit) who is unaware of the IMNCI classification by the investigator. The usual assessment and management protocol of the treating unit will be followed, under guidance from a senior pediatrician. Relevant investigations will be performed to guide diagnosis

Can I refuse to join the study?

You may refuse to participate or withdraw from the study at any time.In both cases your child will be treated in the usual manner in this hospital.

Is there a benefit or harm to be in this study?

There is no evident danger or discomfort involved due to participation in the study, except for a short delay of about 5 to 10 minutes required to complete the IMNCI assessment.

Confidentiality

The data collected from the study will be used for the purpose of the study only.The results of the study are to be published. Personal information of the children participating in the study will be kept confidential.There will not be any disclosure about your childs information without your permission.

Subject Rights

I understood that if I wish further information regarding my childs rights as a research subject,I may contact the hospital where the study is taking place.

INFORMED CONSENT FORM

I have been fully informed about the study and the benefits to my child and the possible harm that can happen.I understand that the doctor will ask questions and examine my child to make sure that it is safe for him/her to enter the study.

This authorization is valid only for this study. “ I have understood and received a copy of the consent form”. I agree for my child’s participation in this research study.

Signature/Thumb Print of Parent/Guardian:

Signature of the investigator:

Witness Signature:

Date:

Principal Investigator:

Address:

Phone:

தகவல் அளிக்கப்பட்ட ஒப்புதல் படிவம்

2 மாதங்கள் முதல் 5 வயது வரையிலுள்ள குழந்தைகளுக்கான IMNCI அட்டவணையை உச்சநிலை மையத்தில் மதிப்பிடுதல்

ஆய்வாளர்கள்:

1. மரு. பெ.வெங்கடேஷ்: முதன்மை ஆய்வாளர்
2. மரு. சி.சுப்புலெட்சுமி, M.D. D.C.H, மேற்பார்வையாளர்
3. மரு. வி. சீதா, M.D. D.C.H, மேற்பார்வையாளர்
4. மரு. K.ஹேமசித்ரா M.D., மேற்பார்வையாளர்
5. மரு. P.ராம்குமார் M.D, மேற்பார்வையாளர்
6. மரு, A.ஸ்ரீதேவி நாராயண் M.D, மேற்பார்வையாளர்

ஒவ்வொரு வருடமும் 10 மில்லியனுக்கும் மேற்பட்ட குழந்தைகள் 5 வயதிற்கு முன்னே இறந்து விடுகின்றன. அவற்றிற்கு சுவாச மண்டல கிருமி நோய்கள், வயிற்றுப்போக்கு, மலேரியா காய்ச்சல், தட்டம்மை, ஊட்டச்சத்து குறைபாடுகள் முக்கிய காரணங்கள் ஆகின்றன.

அதனால் உலக சுகாதார நிறுவனமும், UNICEF-ம் இணைந்து 1992ம் ஆண்டு IMCI (Integrated Management of Childhood Illness) என்ற புதிய திட்டத்தைத் தொடங்கியது. இந்த திட்டத்தின் வழிமுறைகள் இந்தியாவில் பச்சிளம் குழந்தைகளையும் உட்படுத்தி விரிவாக்கப்பட்டு IMNCI (Integrated Management of Neonatal and Childhood Illness) என்று திருத்தி பெயரிடப்பட்டுள்ளது.

IMNCI என்பது குறைந்த பயிற்சி உடைய நலத்திட்ட ஊழியர்களால் குழந்தைகளிடம் உள்ள நோயின் தன்மையை கண்டறியவும் அதற்கு உரிய மருத்துவ உதவியை நல்கும் வண்ணமும் எளிமையாக்கி வடிவமைக்கப்பட்டுள்ளது.

ஆய்வின் நோக்கம்:

வெகு சில ஆய்வுகளே IMNCI-யின் பயன்பாடுகளைக் கண்டறிந்துள்ளன. மேலும் இந்தியாவில் இந்த ஆய்வுகளின் எண்ணிக்கை மிகவும் குறைவு. எனவே இந்த ஆய்வு 2 மாதங்கள் முதல் 5 வயதிற்கான குழந்தைகளின் IMNCIயின் அட்டவணையின் பயன்பாடுகளைக் கண்டறியப் போகிறது. இதுவே தமிழ்நாட்டில் இது போன்ற முதல் ஆய்வாகும்.

ஆராய்ச்சி நடவடிக்கைகள்:

இந்த மருத்துவ மனையை அணுகும் 2 மாதம் முதல் 5 வயது வரையிலான குழந்தைகளை IMNCI அட்டவணை முறையில் வகைப்படுத்திய பின்பு அவற்றை ஒரு குழந்தை நிபுணர் நோய் அறிதல் முறையுடை ஒப்பிட்டு, IMNCI அட்டவணையின் பயன்பாட்டை கண்டறிதல்.

அபாயம் மற்றும் நன்மைகள்:

IMNCI அட்டவணைப்படி நோயுற்ற குழந்தையை மதிப்பீடு செய்யும் போது அக்குழந்தைகளுக்கு 5 முதல் 10 மணித்துளிகள் வரை கால தாமதம் ஏற்படும் என்பதைத் தவிர வேறு வெளிப்படையான ஆபத்தோ அசௌகரியமோ ஏற்படுவதில்லை.

தகவலளிக்கப்பட்ட ஒப்புதல் படிவம்:

இந்த ஆய்வுபற்றி எனக்கு விளக்கமாக எனது தாய்மொழியில் (தமிழ்) சொல்லப்பட்டது. இந்த ஆய்வில் பங்கெடுத்துக் கொள்வதால் எனது குழந்தைக்கு ஏற்படக்கூடிய அபாயங்கள் மற்றும் நன்மைகள் பற்றி எனக்கு விளக்கப்பட்டது. இந்த ஆய்வில் எனது குழந்தையை பங்கெடுத்துக் கொள்ள முழு மனதுடன் சம்மதிக்கிறேன். கேள்விகள் கேட்பதற்கு எனக்கு வாய்ப்பு அளிக்கப்பட்டது.

இந்த ஆய்விலிருந்து கிடைக்கும் முடிவுகளை பயன்படுத்துபவரை கட்டுப்படுத்தாமல் இருக்க நான் சம்மதிக்கிறேன்.

குழந்தையின் பெயர்:-

குழந்தையின் பெற்றோர்/கண்காணிப்பாளர் பெயர்:-

குழந்தையின் பெற்றோர்/கண்காணிப்பாளர் கையொப்பம்:-

தேதி:-

சாட்சியின் பெயர்:-

சாட்சியின் கையொப்பம்:-

தேதி:-

ஆய்வாளர்/ஆய்வு மருத்துவர் பெயர்:

மருத்துவர் கையொப்பம்:

தேதி:-